



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Yogikala Prabhu, Ph.D., 301-761-7789; prabhuyo@niaid.nih.gov. Licensing information may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases (NIAID), 5601 Fishers Lane, Rockville, MD 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

SUPPLEMENTARY INFORMATION: Technology description follows:

Novel Methods of MHC-I - LILRB Checkpoint Inhibition

Description of Technology:

The technology encompasses antibodies and methods that may overcome the shortcomings of commercial checkpoint inhibitors (CPIs). Scientists at NIAID have identified MHC-I specific antibodies that selectively inhibit interactions with inhibitory leukocyte immunoglobulin-like receptors (LILRs) but not T-cell receptors. Administration of the antibodies increased proliferation and activation of both innate and adaptive

immune system cells, and lead to anti-tumor and anti-viral activity in an array of relevant mouse models of disease.

Immune CPIs that target PD-1/PD-L1, CTLA-4 and other well-known molecules can provide significant clinical benefit as part of a mono or combination immunotherapy regimen. However, many patients do not respond to treatment, leading to an ongoing search for novel checkpoint targets. One attractive family of targets are the inhibitory Leukocyte Immunoglobulin-like receptors (LILRB1-5). LILRB1, LILRB2, and LILRB5 can inhibit immune cell function by binding to many MHC-I subtypes. However, LILRB1/2/5 expression is variable and the three members cannot be targeted by any single blocking anti-LILB antibody, possibly limiting the efficacy of targeting LILRBs. NIAID scientists have circumvented these issues by identifying antibodies that can inhibit LILRB function by binding to MHC-I without interfering with T-cell receptor engagement.

To date, the MHC-I specific antibodies have been shown to induce activation and proliferation of human T cells and NK cells in xenogeneic models using NSG mice.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- Anti-tumor checkpoint inhibitor
- Anti-viral checkpoint inhibitor

Competitive Advantages:

- Activation of innate (NK) and adaptive (CD8⁺ and CD4⁺) immune cell types
- Causes proliferation and activation of immune effector cells regardless of target expression in tumors

Development Stage:

- Pre-clinical

Inventors: Ethan M. Shevach, M.D. (NIAID), Abir Panda, Ph.D. (NIAID), David H. Margulies, M.D., Ph.D. (NIAID), and Kannan Natarajan, Ph.D. (NIAID).

Publications: Panda, Abir, et. al. "Cutting Edge: Inhibition of the interaction of NK inhibitory receptors with MHC class I augments anti-viral and anti-tumor immunity." J Immunol. 2020.04.01.437942;

Intellectual Property: HHS Reference No. E-160-2021-0; US provisional application No. 63/262,120 filed on October 5, 2021.

Licensing Contact: To license this technology, please contact Yogikala Prabhu, Ph.D., 301-761-7789; prabhuyo@niaid.nih.gov, and reference E-160-2021-0.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact Yogikala Prabhu, Ph.D., 301-761-7789; prabhuyo@niaid.nih.gov.

Dated: April 12, 2022.

Surekha Vathyam,

Deputy Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.